UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,315	04/21/2004	Joel R. Studin	SDF 04-15	5670

7590 07/09/2007

Stuart D. Frenkel
Suite 330
3975 University Drive
Fairfax, VA 22030

EXAMINER
SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
07/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,315	STUDIN, JOEL R.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Non-Final Office Action, Applicant's Arguments/Remarks, the Declaration under 37 C.F.R. §1.131 and request for extension of time (3 months-granted), all filed 04/13/07 is acknowledged.

Claims 17-29 are pending in this action. Claims 1-16 and 30-54 have previously been cancelled. No claims have been amended herein. Claims 17-29 remain rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17, 19-21 and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang (US Pat. No. 6,528,086 B2).

The instant invention is drawn to a method of treating immunological skin disorders comprising: applying onto an area of skin affected by said skin disorder a fluid, film-forming carrier, having contained therein a steroid, and hardening the carrier into a tangible membrane juxtaposed to said affected area.

Zhang ('086) teaches methods and formulations for dermal drug delivery on a human body surface comprising less than solid anesthetic formulations and delivery systems that can be

applied to the skin or compromised surfaces and subsequently converted to a soft coherent solid state and then peeled off after the anesthetic effect is achieved (see Abstract); (column 1, lines 9-23). The formulation comprises a topically delivered drug, a conversion agent and a vehicle medium or carrier, wherein the drug is dispersed in the carrier (col. 3, lines 20-22). At the time of application of the formulation to the skin, the formulation is in a less-than-solid phase. At the conclusion of the treatment, the formulation is a coherent, soft solid that can be cleanly peeled from the skin (col. 3, lines 23-29).

The formulation contains active ingredients of topical and local anesthetic agents and systemic circulation and regional tissue drugs of analgesics, hormones and anti-inflammatory agents (col. 14, lines 55-61).

According to Zhang, the topically delivered drug or pharmaceutical can be a single drug, such as a single local anesthetic or a combination of drugs (*i.e.*, eutectic mixture of lidocaine and tetracaine). The drug may be dispersed throughout the formulation in a solid form, dissolved in oil droplets, which are dispersed in the vehicle medium, or in aqueous solution within the vehicle medium. The drug should be capable of transdermal delivery. The vehicle medium facilitates application of the formulation and delivery of the drug. Permeation enhancers may also be added (col. 3, lines 10-58).

The conversion agent provides the formulation with the ability to change from one phase to another more solid and coherent phase, such as from a liquid or cream to a soft solid. The formulation is applied to a patient's skin in such a way as to form a continuous layer of formulation. When the phase change occurs, the solidified formulation is more easily removed from the patient's skin. The formulation does not leave behind residues or films. Zhang teaches

that a unique feature of his invention is that the solid phase is coherent and has certain strength so it can be peeled off the body surface as a layer, leaving little residual formulation. The formulation will be flexible and not brittle (see col. 3, line 59 – col. 4, line 9).

Zhang teaches the use of polyvinyl alcohol as an ingredient in the cream formulation of his invention (col. 4, lines 22-32).

Cellulose derivatives are disclosed at column 12, lines 13-25.

Various drugs and pharmaceutical agents can be included in the formulation, such as dermatological agents; drugs for promoting wound healing; drugs for treating warts and moles; drugs for treating ulcerated skin; drugs for treating insect bites and minor cuts; anti-inflammatory agents (e.g., *corticosteroids*); analgesics (narcotic agents, *steroids*); vitamins; agents for treating necrotic tissues and dermal ulcers used in debridement (e.g. collagenase); hormones and the like (col. 11, lines 16 – col. 14, line 64).

The various Tables and examples demonstrate different applications of the invention. For example, Table A (Formulation I) at column 7, shows a formulation comprising a pharmaceutical agent (eutectic mixture), polyvinyl alcohol, glycerol, lecithin, Water Lock® and water in various percentage weights wherein it states that Formulation I should be easy to apply and remove (i.e., in form of cream, paste) when applied to the skin, but should form a solid gel so that it can be easily 'peeled off' the skin without leaving a mess on the skin. Tables B and onwards demonstrate anesthetic formulations comprising mixtures of anesthetics and ingredients.

Zhang teaches that one of the advantages of his invention is that it obviates the need to remove the cream from the skin by extensive washing or cleansing of the skin. When the desired anesthetic effect is achieved, the solid gel is peeled off the skin area, leaving virtually no residual

mess on the skin. The skin area is anesthetized and if desired can be subjected to a medical treatment or procedure (col. 9, line 45 – col. 10, line 9).

Zhang teaches drug formulations and delivery systems that can be applied to and then peeled off the skin and/or off compromised human body surfaces after the drug delivery is achieved. There is no significant distinction observed between the instant method and the methods of the prior art since Zhang explicitly teaches methods of drug delivery comprising active ingredients, such as anti-inflammatory agents (e.g., corticosteroids) and dermal-treating drugs in combination with fluid carriers and conversion agents wherein the formulation can be cleanly peeled off the skin.

Thus, given the explicit teachings of Zhang delineated above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang (US Pat. No. 6,528,086 B2) as applied to claims 17, 19-21 and 23-29 above and further in view of Herb *et al.* (U.S. Pat. No. 5,534,246).

The instant invention is drawn to a method of treating immunological skin disorders comprising: applying onto an area of skin affected by said skin disorder a fluid, film-forming carrier, having contained therein a steroid, and hardening the carrier into a tangible membrane juxtaposed to said affected area.

The teachings of Zhang are delineated above.

Zhang does not teach skin disorders, such as dermatitis or psoriasis and does not teach phenyltrimethicone.

Herb *et al.* ('246) teach topically-effective compositions comprising topically-active drugs that include dermatitis medications and psoriasis agents (see column 9, lines 46-51); (col. 10, lines 11-12). Herb *et al.* also teach that nonvolatile organic compounds, such as phenyltrimethicone can also be added to the compositions to provide an aesthetic effect or for adjusting the refractive index (col. 12, lines 41-54); (Claims 20 & 35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the dermatitic/psoriatic medications and phenyltrimethicone organic compound as taught by Herb *et al.* within the delivery formulations of Zhang. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Herb *et al.* explicitly teach that suitable and effective active agents for use in their formulation include dermatitis and psoriasis medications to treat skin conditions and also teach that organic compounds, such as phenyltrimethicone are added to the composition to provide either aesthetically-based effects or adjustment of refractive index values. The expected result would an enhanced and effective method for treating an array of skin conditions.

Pertinent Art

Prior Art made of record, not relied upon and deemed relevant by the Examiner:

US Patent No. 5,446,070 *Mantelle* 08/1995

US Patent No. 4,937,078 *Mezei et al.* 06/1990

Response to Arguments

Applicant's arguments filed 04/13/07 have been fully considered but they are not persuasive.

- **35 U.S.C. §103(a) rejection**:

Applicant argued, "Zhang does not teach a method of treating a skin disorder by applying a film-forming carrier which contains a steroid. In contrast, Zhang discloses a wide variety of useful drugs, which may be applied, to skin using the drug delivery method of Zhang. Although Zhang does disclose the use of a corticosteroid as a potential anti-inflammatory agent, Zhang does not specifically disclose the use of a film-forming carrier containing a steroid in a method to treat immunological disorders."

Applicant's arguments have been considered, but were not persuasive. The methods and devices taught by Zhang are explicitly employed for the treatment of dermal conditions. The formulation of Zhang comprises a topically delivered drug, a conversion agent and a vehicle medium or carrier, wherein the drug is dispersed in the carrier (col. 3, lines 20-22). The formulation contains active ingredients of topical and local anesthetic agents and systemic circulation and regional tissue drugs of analgesics, hormones and anti-inflammatory agents (col. 14, lines 55-61). Thus, Zhang explicitly teaches use of a drug that is dispersed in a carrier. Zhang also teaches that suitable drugs include anti-inflammatory agents, as also noted by Applicant.

Applicant argued, "Applicant submits herewith a Declaration under 37 C.F.R. § 1.131, showing the preparation and use of Scar Guard in the treatment of skin disorders, such as psoriasis. According to the Declaration, Exhibit A shows the formulation of Scar Guard, which contains a corticosteroid in a film-forming carrier, and Exhibit C shows the testing of Scar Guard on psoriasis, both prior to September 28, 1999, the earliest filing date of Zhang et al. See the Declaration of Joel R. Studin at paragraphs 5-7. In as much as the Applicant has reduced the present invention to practice prior to the effective date of the Zhang et al. reference, Zhang et al. is no longer an effective reference against the invention as claimed. In regards to claims 19-21 and 23-29, submitted herewith is the Declaration of Joel R. Studin under 37 C.F.R. § 1.131, showing the preparation of Scar Guard prior to September 28, 1999, the earliest priority date ofZhang et al. As Applicant has mentioned hereinabove, the Declaration shows the formulation and testing of Scar Guard prior to September 28, 1999. See the Declaration of Joel R. Studin at paragraphs 5-7. In as much as the Applicant has reduced the present invention to practice prior to the effective date of the Zhang et al. reference, Zhang et al. is no longer an effective reference against the invention as claimed."

The Declaration under 1.131 has been considered but was not persuasive. The Declaration presented does not demonstrate a data comparison between the closest prior art and that of the instant invention. The Declaration does not set forth any distinctions obtained between the present invention and that of the Zhang reference. The data presented only shows the ingredients employed in the ScarGuard and states that clinical testing data was done. No additional data has been presented to determine a side-by-side comparison with the prior art references, which could define the distinctions argued by Applicant. Thus, the Declaration was not found persuasive.

With regard to the rejection of claims 18 & 22 over Zhang in view of Herb ('246), Applicant argued, "The Declaration under 37 C.F.R. § 1.131 shows the preparation and testing of Scar Guard, prior to September 28, 1999, the earliest priority date of Zhang. In as much as the Applicant has reduced the present invention to practice prior to the effective date of the Zhang et al. reference, Zhang et al. is no longer an effective reference against the invention as claimed. Herb does not teach or suggest the use of a topically effective steroid in a film-forming carrier."

These arguments were not persuasive. As noted above, the Declaration presented does not establish a side-by-side comparison of the formulations of the prior art with that of the instant invention. Nor have any unexpected results been demonstrated through Applicant's Declaration. Thus, the Declaration was not persuasive, rendering the Zhang reference applicable to the instant claims. With regards to Herb, the Zhang reference initially teaches the use of a steroid in a film-forming carrier and thus, meets the limitations of the claims. Moreover, the Herb reference teaches compositions containing phenyltrimethicone for dermatitic/psoriatic applications and thus, meets this deficiency of the Zhang reference.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

Art Unit 1615

July 5, 2007

HUMERA N. SHEIKH
PRIMARY EXAMINER

hns